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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,061	02/20/2004	Vincent Sullivan	035510/303994(P-5972)	6766

47656 7590 07/13/2006

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,061	SULLIVAN ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-24, drawn to a pharmaceutical composition, classified in class 424, subclass 1.13.

II. Claims 25-48, drawn to a method of preparing a pharmaceutical composition, classified in class 424, subclass 1.13.

III. Claims 49-60, drawn to a method of treatment, classified in class 424, subclass 1.13.

IV. Claims 61-65, drawn to a method of eliciting an immune response, classified in class 424, subclass 1.13.

V. Claims 66-68, drawn to a prime-boost regimen, classified in class 424, subclass 1.13.

VI. Claims 69-71, 74 and 75, drawn to a vaccine composition, classified in class 424, subclass 184.1.

VII. Claim 72 and 73, drawn to a method of preparing a vaccine composition, classified in class 424, subclass 184.1.

Claim 1 links inventions I and III-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 1. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claim will be rejoined and fully examined for

patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other for the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make another and materially different product, such as a chemotherapeutic composition.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product, such as a chemotherapeutic agent.

Inventions I and IV are related as product and process of use. In the instant case, the process for using the product as claimed can be practiced with another materially different product, such as an adjuvant.

Inventions I and V are related as product and process of use. In the instant case, the product as claimed can be used in a materially different process of using that product, such as transmucosal administration.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group I is directed to a pharmaceutical composition while group VI is directed to a vaccine composition.

Inventions I and VII are unrelated. In the instant, Group I is directed to a pharmaceutical composition while Group VII is directed to a method of preparing a vaccine composition.

Inventions II and III are unrelated. In the instant case, Group II is directed to a method of preparing a pharmaceutical composition while group III is directed to a method of treatment.

Inventions II and IV are unrelated. In the instant case, Group II is directed to a method of preparing a pharmaceutical composition while group IV is directed to a method of eliciting an immune response.

Inventions II and V are unrelated. In the instant case, Group II is directed to a method of preparing a pharmaceutical composition while group V is directed to a prime-boost regimen.

Inventions II and VI are unrelated. In the instant case, Group II is directed to a method of preparing a pharmaceutical composition while group VI is directed to a vaccine composition.

Inventions II and VII are unrelated. In the instant case, Group II is directed to a method of preparing a pharmaceutical composition while group VII is directed to a method of preparing a vaccine composition.

Inventions III and IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group III is directed to a method of treatment while Group IV is directed to a method of eliciting an immune response.

Inventions III and V are directed to related processes. In the instant case, Group III is directed to a method of treatment while Group V is directed to a prime-boost regimen.

Inventions III and VI are unrelated. In the instant case, Group III is directed to a method of treatment while group VI is directed to a vaccine composition.

Inventions III and VII are unrelated. In the instant case, Group III is directed to a method of treatment while group VII is directed to a method of preparing a vaccine composition.

Inventions IV and V are directed to related processes. In the instant case, Group IV is directed to a method of eliciting an immune response while Group V is directed to a prime-boost regimen.

Inventions IV and VI are unrelated. In the instant case, Group IV is directed to a method of eliciting an immune response while group VI is directed to a vaccine composition.

Inventions IV and VII are unrelated. In the instant case, Group IV is directed to a method of eliciting an immune response while group VII is directed to a method of preparing a vaccine composition.

Inventions V and VI are unrelated. In the instant case, Group V is directed to a prime-boost regimen while group VI is directed to a vaccine composition.

Inventions V and VII are unrelated. In the instant case, Group V is directed to a prime-boost regimen while group VII is directed to a method of preparing a vaccine composition.

Inventions VI and VII are related as process of making and product made. In the instant case the process as claimed can be used to make another and materially different product, such as a chemotherapeutic composition.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species:

Group I:

- Species I - Election of a fluid:
    a. Gas (Claim 10)
    b. Liquid (Claim 11)
- Species II - Election of a therapeutic agent:
    a. Immunogenic agent (Claim 17)
    b. Insulin (Claim 20)

Group II:

- Species I - Election of a fluid:
    a. Gas (Claim 34)
    b. Liquid (Claim 35)
- Species II - Election of a therapeutic agent:
    a. Immunogenic agent (Claim 41)
    b. Insulin (Claim 44)

Group III:

- Species I - Election of a route of administration:
    a. Intranasal (Claims 51 and 60)
    b. Mucosal (Claim 52)

Group IV:

- Species I - Election of an immunogenic composition:
    a. influenza vaccine comprising a nucleic acid (Claim 64)
    b. Influenza vaccine comprising inactivated influenza virus particles or a subunit of a flu virus (Claim 65)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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